

Minutes of Meeting

Alabama Medicaid Agency Pharmacy and Therapeutics Committee

February 11, 2009

Attendees: Chairman Ben Main, Dr. Lucy Culpepper, Dr. Gerard J. Ferris, Dr. Michelle Freeman, Ms. Vicki Little Faulk, Dr. Kelli Littlejohn, Dr. Robert Moon, Ms. Latonage Porter, Dr. Tina Hisel and Dr. Lauren Biczak

Absent: Dr. Nancy Sawyer; Dr. Joseph Thomas; Dr. Chivers R. Woodruff

1. OPENING REMARKS

Chairman Main called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 9:14 a.m.

2. APPROVAL OF MINUTES

Chairman Main asked if there were any corrections to the minutes from the December 10, 2008 P&T Committee Meeting.

There were no objections. Dr. Culpepper made a motion to approve the minutes as presented and Dr. Freeman seconded to approve the minutes. The minutes were unanimously approved.

3. PHARMACY PROGRAM UPDATE

The Agency implemented its routine Preferred Drug List quarterly update on January 2, 2009; the next quarterly update will be on April 1, 2009. The radiology prior authorization program will begin on March 2, 2009. Any radiological services claims without prior authorization will be denied after April 1, 2009. An ALERT can be found on the Alabama Medicaid website and was sent out to all physicians. The contractor, MedSolutions, will be sending out additional information.

A Positive Antipsychotic Management (PAM) update was provided. At the December 10, 2008 meeting, Dr. Littlejohn reported that the Agency was reviewing preliminary results from the medical chart review of children ages 0-4 years who had received a second generation antipsychotic. A PAM workgroup meeting is scheduled for February 25, 2009 to review the results as well; another update will be given at the next Pharmacy & Therapeutics (P&T) Committee meeting.

The Agency recently held its first web conference via iLinc for the Drug Utilization Review Board. The Agency would like to offer the iLinc option during future P&T Committee meetings to its members as well. Members attending the meeting remotely would have the ability to see the contractor speaker, presenting manufacturers, other committee members, documentation, ask questions via chat (and conference phone line) and cast their

vote. The goal is to implement the service in time for the August 2009 or November 2009 P&T Committee meeting; more information will be forthcoming

Dr. Littlejohn reminded the Committee that the prior authorization criteria for each class reviewed during the meeting could be found in their packets along with the P&T Committee reference document.

Dr. Littlejohn reiterated the policy for meeting with members of the manufacturing industry, including manufacturer solicitation of P&T Committee members regarding drugs included in upcoming P&T meetings. She asked that members report solicitation to herself or Ms. Thomas immediately.

Dr. Littlejohn introduced the Pharmacy Clinical Support contractor representatives, Dr. Tina Hisel and Dr. Laureen Biczak with Goold Health Systems.

Dr. Littlejohn reminded the manufacturer representatives of the policy regarding the submission of written and oral comments prior to P&T Committee meetings. She noted that the letters received by each company refer the manufacturer to the Medicaid website, where a full copy of the policy can be found. She reviewed portions of the policy, including the submission of clinical data derived from abstracts and poster presentations. According to the policy, poster board presentations and abstracts cannot be included for the review of the class or drug if no full study has been conducted and published in peer reviewed literature.

Dr. Littlejohn welcomed the Agency's nursing group who were attending the meeting as part of their continuing education initiative.

Mr. Main thanked the clinical contractor for providing updated peer-reviewed information and mentioned that the class reviews for the current meeting are re-reviews.

4. ORAL PRESENTATIONS BY MANUFACTURERS/MANUFACTURERS' REPRESENTATIVES

One five-minute verbal presentation was made on behalf of a pharmaceutical manufacturer. Dr. Littlejohn explained the process and timing system for the manufacturers' oral presentations. The drug and corresponding manufacturer is listed below in the appropriate therapeutic class.

5. PHARMACOTHERAPY CLASS REVIEWS (Please refer to the website for full text reviews.)

The pharmacotherapy reviews began at approximately 9:25 a.m.

Centrally Acting Skeletal Muscle Relaxants: American Hospital Formulary Service (AHFS) 122004

Manufacturer comments on behalf of these products:

Zanaflex® (tizanidine) - Acorda Therapeutics

Dr. Hisel commented that the skeletal muscle relaxants were last reviewed as one class in October 2005. Since then, the skeletal muscle relaxants have been further divided into four (4) subclasses. The centrally acting skeletal muscle relaxants are used to treat two different types of conditions: spasticity from upper motor neuron syndromes and muscular pain/spasms from peripheral musculoskeletal conditions. Spasticity is associated with

a number of central nervous system disorders including stroke, multiple sclerosis, as well as brain and spinal cord injuries. The goal of therapy is to improve functioning, as well as to alleviate pain and facilitate daily care activities. Tizanidine is a α_2 -adrenergic agonist and presumably reduces spasticity by increasing presynaptic inhibition of motor neurons. The other centrally acting skeletal muscle relaxants are used for the treatment of acute pain/discomfort from musculoskeletal disorders. The mechanism of action is unclear, but may be related to the sedative properties of the agents. Table 1 lists the centrally acting skeletal muscle relaxants included in the review. All centrally acting skeletal muscle relaxants are available in a generic formulation with the exception of metaxalone. The carisoprodol products were placed on prior authorization in January 2007 through P&T and DUR review due to the potential for abuse. Additionally, an extended-release cyclobenzaprine product (Amrix®) has become available since this class was last reviewed.

Current guidelines that incorporate the use of the centrally acting skeletal muscle relaxants are summarized in Table 2. Two guidelines on low back pain were updated in 2007. These guidelines recommend acetaminophen or non-steroidal anti-inflammatory drugs as the first-line medication. Centrally acting skeletal muscle relaxants are recommended as second-line treatment in select cases of moderate to severe acute low back pain. They are not recommended for mild to moderate acute low back pain or chronic use in sub-acute or chronic low back pain. Guidelines on the diagnosis and management of multiple sclerosis recommend tizanidine only if treatment with baclofen or gabapentin is unsuccessful or side effects are intolerable. Guidelines for the management of stroke rehabilitation recommend considering the use of tizanidine for spasticity resulting in pain, poor skin hygiene, or decreased function.

Table 3 outlines the FDA-approved indications for the centrally acting skeletal muscle relaxants. The pharmacokinetics and drug interaction sections have been updated as necessary. There are many drug interactions to consider with regards to tizanidine. Tizanidine is primarily metabolized by the CYP4501A2 isoenzyme. Medications that inhibit the CYP4501A2 isozyme may increase serum levels of tizanidine and lead to excessive sedation and hypotension because it is an α_2 -adrenergic agonist.

The adverse drug events reported with the centrally acting skeletal muscle relaxants are listed in Table 6. Adverse events are problematic with the centrally acting skeletal muscle relaxants with drowsiness and dizziness being common with all of the agents. There have been post-marketing reports of dependence, withdrawal and abuse with prolonged use of carisoprodol; most cases have occurred in patients who have had a history of addiction or who used carisoprodol in combination with other drugs with abuse potential. Withdrawal symptoms have been reported following abrupt cessation after prolonged use. Tizanidine occasionally causes liver injury, most often hepatocellular in type. Monitoring of aminotransferase levels is recommended during the first 6 months of treatment and periodically thereafter.

The dosing and administration section has been updated. Because of the risk of dependence, withdrawal and abuse, carisoprodol should not be used for more than 2-3 weeks.

The comparative clinical trials with centrally acting skeletal muscle relaxants are listed in Table 8. Only one of the studies added to the clinical packet was recently published (Ralph, et al. 2008). The study was a comparison between carisoprodol and placebo. Although the centrally acting skeletal muscle relaxants have been available for many years, there are limited head-to-head trials in the treatment of spasticity and musculoskeletal disorders. Tizanidine has consistently been found to be more effective than placebo in clinical trials. Additionally, there are limited head-to-head trials comparing tizanidine to other anti-spasticity agents.

Dr. Hisel concluded that the centrally acting skeletal muscle relaxants are indicated for the treatment of spasticity and pain/discomfort associated with musculoskeletal disorders. Tizanidine, when used for the

treatment of spasticity, has consistently been found to be more effective than placebo in clinical trials. However, clinical trials have enrolled small numbers of patients and data to support the long-term use of tizanidine are limited. There are limited head-to-head trials comparing tizanidine to other anti-spasticity agents. Guidelines on the diagnosis and management of multiple sclerosis recommend tizanidine only if treatment with baclofen or gabapentin is unsuccessful or side effects are intolerable. Guidelines for the management of stroke rehabilitation recommend considering the use of tizanidine for spasticity resulting in pain, poor skin hygiene or decreased liver function. Tizanidine may cause liver injury and monitoring of aminotransferase levels is recommended during the first 6 months of therapy. To date, there is insufficient evidence to conclude that tizanidine exhibits clinical advantages over other anti-spasticity agents. The centrally acting skeletal muscle relaxants are also effective for the treatment of musculoskeletal disorders, including relief of non-specific low back pain. Guidelines on the treatment of low back pain recommend acetaminophen or non-steroidal anti-inflammatory drugs as the first-line medication. Centrally acting skeletal muscle relaxants are recommended as second-line treatment in select cases of moderate to severe acute low back pain. Adverse events are problematic with this class, particularly drowsiness and dizziness. Due to dependence, withdrawal and abuse, carisoprodol should only be used short-term for no more than 2-3 weeks. There is no compelling evidence to indicate that the centrally acting skeletal muscle relaxants differ in efficacy or safety for the treatment of low back pain.

Therefore, all brand centrally acting skeletal muscle relaxants within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand centrally acting skeletal muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee members to mark their ballots.

Direct-acting Skeletal Muscle Relaxants: AHFS 122008

Manufacturer comments on behalf of these products:

None

Dr. Hisel commented that the direct-acting skeletal muscle relaxants were last reviewed in October 2005. Dantrolene is the only direct-acting skeletal muscle relaxant currently available in this class. It is used to control the manifestations of clinical spasticity resulting from upper motor neuron syndromes and to treat or prevent malignant hyperthermia, which is a life-threatening, genetically based disorder that occurs in susceptible individuals after exposure to certain drugs. While some treatments for spasticity, such as baclofen and tizanidine, act centrally on the spinal cord or brain stem, dantrolene acts directly on the skeletal muscles. Dantrolene capsules are available in a generic formulation.

Current guidelines that incorporate the use of the direct-acting skeletal muscle relaxants are listed in Table 2. The guidelines are identical to those in the centrally acting skeletal muscle relaxants class review. Guidelines on the diagnosis and management of multiple sclerosis recommend dantrolene only if treatment with baclofen or gabapentin is unsuccessful or side effects are intolerable.

The FDA-approved indications for dantrolene are listed in Table 3. The pharmacokinetic, drug interaction, adverse event and dosing and administration sections have been updated. Dantrolene has the potential to cause

fatal or non-fatal hepatotoxicity, which has led to the placement of a boxed warning in the prescribing information. The risk of hepatic injury appears to be greater in females, in patients over 35 years of age and in patients taking other medication(s) in addition to dantrolene. The boxed warnings are located in Tables 7 and 8.

Comparative clinical trials evaluating the safety and efficacy of the direct-acting skeletal muscle relaxants are listed in Table 10. Clinical trials with dantrolene have been of short duration and enrolled small numbers of patients. However, dantrolene has consistently been found to be more effective than placebo in clinical trials. There are no head-to-head trials comparing dantrolene to other antispasticity agents, and it is difficult to draw conclusions on the efficacy of dantrolene as no validated outcome measures were used in clinical trials. Dantrolene is the treatment of choice for malignant hyperthermia. When used, this treatment is emergent in nature and occurs in the inpatient or outpatient operative setting. However, no controlled trials were found in the peer-reviewed literature regarding the use of dantrolene for malignant hyperthermia.

Dr. Hisel concluded that dantrolene is an effective treatment for spasticity and is the treatment of choice for malignant hyperthermia. Although dantrolene has consistently been found to be more effective than placebo in clinical trials, there are no head-to-head trials comparing dantrolene to other antispasticity agents. Guidelines on the diagnosis and management of multiple sclerosis recommend dantrolene only if treatment with baclofen or gabapentin is unsuccessful or side effects are intolerable. Dantrolene has the potential to cause fatal or non-fatal hepatotoxicity. Careful monitoring of liver function tests and patient selection is necessary.

Therefore, all brand direct-acting skeletal muscle relaxants within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand direct-acting skeletal muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There was no further discussion on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

GABA-derivative Skeletal Muscle Relaxants: AHFS 122012

Manufacturer comments on behalf of these products:

None

Dr. Hisel commented that the GABA-derivative skeletal muscle relaxants were last reviewed in October 2005. Baclofen is the only GABA-derivative skeletal muscle relaxant currently available in this class. It is FDA-approved for the treatment of spasticity. Baclofen is an analog of gamma aminobutyric acid (GABA) and inhibits both monosynaptic and polysynaptic reflexes at the spinal level to cause muscle relaxation. Baclofen tablets are available in a generic formulation.

Current guidelines that incorporate the use of the GABA-derivative skeletal muscle relaxants are listed in Table 2. The same four guidelines discussed previously are listed here. Guidelines on the diagnosis and management of multiple sclerosis recommend initial treatment with baclofen or gabapentin for bothersome regional or global spasticity or spasms.

The pharmacokinetics and drug interaction sections have been updated as necessary. Adverse drug events are listed in Table 6. Abrupt withdrawal of oral baclofen can lead to hallucinations and seizures. Additionally, serious sequelae, such as high fever, altered mental status, exaggerated rebound spasticity and muscle rigidity may occur if intrathecal baclofen is abruptly discontinued. Therefore, a boxed warning for the intrathecal injection has been added to the prescribing information and is listed in Table 7. The dose of oral and intrathecal baclofen should be reduced slowly when the drug is discontinued.

Comparative clinical trials with the GABA-derivative skeletal muscle relaxants are listed in Table 9. Baclofen has been shown to be an effective treatment option for muscular spasms due to disorders such as multiple sclerosis, cerebral palsy, and brain/spinal cord injuries. It has consistently been found to be more effective than placebo in clinical trials. However, there are limited head-to-head trials comparing baclofen to other antispasticity agents.

Dr. Hisel concluded that baclofen is an effective treatment option for muscular spasms due to conditions such as multiple sclerosis, cerebral palsy and brain/spinal cord injuries. It has consistently been found to be more effective than placebo in clinical trials. However, there are limited head-to-head trials comparing baclofen to other antispasticity agents. Guidelines on the diagnosis and management of multiple sclerosis recommend initial treatment with baclofen or gabapentin for bothersome regional or global spasticity or spasms. Serious sequelae may occur if intrathecal baclofen is abruptly discontinued. Therefore, the dose of baclofen (both oral and intrathecal) should be reduced slowly when the drug is discontinued. To date, there is insufficient evidence to conclude that baclofen exhibits clinical advantages over other antispasticity agents.

Therefore, all brand GABA-derivative skeletal muscle relaxants within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand GABA-derivative skeletal muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Skeletal Muscle Relaxants, Miscellaneous: AHFS 122092

Manufacturer comments on behalf of these products:

None

Dr. Hisel commented that the miscellaneous skeletal muscle relaxants were last reviewed in October 2005. Orphenadrine is the only skeletal muscle relaxant that is currently available in this class. It is FDA-approved for the relief of discomfort associated with acute, painful musculoskeletal disorders. Orphenadrine is available in a generic formulation.

Guidelines that incorporate the use of the miscellaneous skeletal muscle relaxants are summarized in Table 2. The guidelines on the treatment of low back pain were reviewed previously and recommend miscellaneous skeletal muscle relaxants as a second-line treatment in select cases of moderate to severe acute low back pain.

The pharmacokinetic, drug interaction, adverse event, and dosing and administration sections have been updated as necessary. The adverse events associated with orphenadrine are mainly due to the mild anticholinergic action of this agent and are usually associated with higher doses. Orphenadrine has been chronically abused for its euphoric effects and the mood elevating effects may occur at therapeutic doses.

Comparative clinical trials with orphenadrine are listed in Table 8. Orphenadrine is an effective treatment for musculoskeletal disorders, including the short-term symptomatic relief of non-specific low back pain. It has been found to be more effective than placebo. However, there were no published head-to-head trials found in the medical literature comparing orphenadrine to other skeletal muscle relaxants.

Dr. Hisel concluded that orphenadrine is an effective treatment for musculoskeletal disorders, including the short-term symptomatic relief of non-specific low back pain. Guidelines on the treatment of low back pain recommend acetaminophen or non-steroidal anti-inflammatory drugs as the first-line medication. Skeletal muscle relaxants are recommended as second-line treatment in select cases of moderate to severe acute low back pain. There are no published head-to-head trials comparing orphenadrine to other skeletal muscle relaxants. Orphenadrine has been chronically abused for its euphoric effects which may occur at therapeutic doses.

Therefore, all brand miscellaneous skeletal muscle relaxants within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand miscellaneous skeletal muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Opiate Agonists: AHFS 280808

Manufacturer comments on behalf of these products:

None

Dr. Hisel commented that the opiate agonists were last reviewed in October 2005. Pain management is multifaceted and may incorporate both pharmacologic and non-pharmacologic treatments. There are numerous pharmacologic agents available to help manage pain, including the opiate agonists. There are several opioid receptors within the central nervous system and peripheral tissues, including mu, delta, kappa, and sigma. Opiate agonists are selective for the mu receptor and are the most potent analgesics. Opiate agonists have no ceiling to their analgesic effect; the degree of analgesia is only limited by dose-related adverse events. Table 1 lists the opiate agonists that are included in this review. The sustained-release opiate agonists are not included in this review as they are already included in the Alabama Medicaid Prior Authorization Program, which is outside of the Preferred Drug List. Most of the products are available in a generic formulation with the exception of oxymorphone, propoxyphene napsylate and remifentanyl.

Guidelines that incorporate the use of the opiate agonists are summarized in Table 2. The guidelines that have been included focus on cancer pain management, chronic non-cancer pain management and treatment for opioid

addition. The ESMO (European Society for Medical Oncology) clinical recommendations, which focus on cancer pain, were updated in 2008. These guidelines recommend mild opiates for mild to moderate cancer pain, and strong opiates for moderate to severe pain. Doses should be titrated to effect as rapidly as possible with around-the-clock dosing and as-needed breakthrough doses to manage transient pain exacerbations. There has also been an update of the American Society of Interventional Pain Physicians Guidelines in 2008, which focus on the management of chronic non-cancer pain. This guideline states that the evidence for the effectiveness of long-term opioids in reducing pain and improving the functional status for 6 months or longer is variable, and the strength of the available evidence is weak. A second guideline released jointly by the Veterans Administration (VA) and Department of Defense (DoD) on the management of opioid therapy for chronic pain recommend opiates for moderate to severe pain that has failed to adequately respond to other non-opioid therapeutic interventions.

The FDA-approved indications for the opiate agonists are listed in table 3, which include pain, supplement to anesthesia, cough, headache, and opioid dependence. The pharmacokinetic, drug interaction, adverse drug event, and dosing and administration sections have been updated as necessary. On February 6, 2009, the FDA sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of the drugs continue to outweigh the risks. The affected opioid drugs include brand name and generic products and are formulated with the active ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. The first of several meetings will begin on March 3, 2009 and will continue into late spring or early summer. Several boxed warnings exist with the opiate agonists, including propoxyphene, morphine injection, transmucosal and transdermal fentanyl, methadone, and high-potency hydromorphone injection, which are listed in Tables 7 through 12.

The comparative clinical trials with the opiate agonists are listed in Table 14. Several new studies have been added to the clinical packet since this class was last reviewed. New studies on acute pain management have demonstrated similar efficacy among the opiate agonists for the acute treatment of pain. New clinical trials and meta analyses evaluating the opiate agonists for chronic pain management have also been added to the clinical packet. The available evidence is highly variable for the long-term treatment of non-cancer pain.

Dr. Hisel concluded that there is no standard opiate regimen that will satisfy the pain needs of all patients. Opiate selection should take into account pain etiology, pain quality and severity, anticipated duration of therapy, routes of administration, and comorbid conditions. Opiate agonists have no ceiling to their analgesic effect; the degree of analgesia is only limited by dose-related adverse events. Guidelines for the management of non-cancer pain recommend opiates for moderate to severe pain. Guidelines for the management of cancer pain recommend mild opiates for mild to moderate pain, and strong opiates for moderate to severe pain. Current guidelines for cancer and non-cancer pain do not give preference to one opiate over another. Numerous clinical trials have demonstrated similar efficacy among the opioid agonists for the treatment of acute pain. However, the available evidence is highly variable for the long-term (>6 months) treatment of non-cancer pain.

Therefore, all brand opiate agonists within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand opiate agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Dr. Moon asked if the FDA notice pointed out a particular mechanism of diversion that was the concern. Dr. Hisel read a section from the letter, mentioning that despite current risk management efforts, the rates of misuse and abuse and of accidental overdose of opioids have risen over the past decade. Dr. Littlejohn stated that she had brought a copy of the FDA statement and offered to supply it to Committee members.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Opiate Partial Agonists: AHFS 280812

Manufacturer comments on behalf of these products:

None

Dr. Hisel commented that the opiate partial agonists were last reviewed in October 2005. The opiate partial agonists affect different receptors than the opiate agonists. Butorphanol, nalbuphine, and pentazocine act as mu receptor antagonists and kappa receptor agonists. Buprenorphine is a kappa receptor antagonist and partial mu receptor agonist. It is able to block the effects of morphine and other opioids, while offering mild opioid-like effects. Naloxone is a competitive antagonist at the mu receptor and lacks any mu receptor efficacy. It has been combined with opiate partial agonists to reduce the risk of abuse. Opiate partial agonists generally have a ceiling to their analgesic effect. Table 1 lists the opiate partial agonists that are included in this review. All opiate partial agonists are available in a generic formulation, with the exception of buprenorphine/naloxone combination and pentazocine injection.

Guidelines that incorporate the use of the opiate partial agonists are summarized in Table 2. These are the same guidelines that were discussed in the opiate agonist class review. These guidelines do not differentiate the opiate agonists from the opiate partial agonists; therefore the recommendations are the same as those that were covered in the last class review. Dr. Hisel pointed out that, although not new, one additional guideline has been added to this class review regarding the use of buprenorphine in the treatment of opioid addiction.

Table 3 lists the FDA-approved indications for the opiate partial agonists. The pharmacokinetic, drug interaction, adverse drug event, and dosing and administration sections have been updated. The boxed warning for pentazocine/naloxone is listed in Table 7.

The comparative clinical trials with the opiate partial agonists are listed in Table 9. Several new clinical trials have been added for opioid dependence. There were few clinical trials in the medical literature directly comparing the opiate partial agonists to each other or to opiate agonists.

Dr. Hisel concluded that there is no standard opiate regimen that will satisfy the pain needs of all patients. Guidelines for the management of non-cancer pain recommend opiates for moderate to severe pain. Guidelines for the management of cancer pain recommend mild opiates for mild to moderate pain, and strong opiates for moderate to severe pain. Current guidelines for cancer and non-cancer pain do not give preference to one opiate over another. There are limited head-to-head trials with the opiate partial agonists.

Therefore, all brand opiate partial agonists within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand partial opiate agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Selective Serotonin Agonists: AHFS 283228

Manufacturer comments on behalf of these products:

None

Dr. Hisel commented that the selective serotonin agonists were last reviewed in February 2007. The selective serotonin agonists (triptans) are FDA-approved for the treatment of acute migraines, with or without aura. They are potent, highly selective 5-HT₁ receptor agonists, with no significant affinity for other 5-HT subgroups. The selective serotonin agonists stimulate receptors located on cerebral vessels to redistribute blood flow and relieve pain. The selective serotonin agonists are a very homogenous group of agents with respect to efficacy, pharmacology and safety. There are currently 7 triptans approved for use in the U.S. In April 2008, a fixed-dose combination tablet containing sumatriptan and naproxen sodium was approved by the FDA for the treatment of migraines (Treximet[®]), which is also included this review. Table 1 lists the selective serotonin agonists that are included in this review. Since the last review, all sumatriptan formulations have become available in a generic formulation and are the only generic agents in this class.

The guidelines that incorporate the use of the selective serotonin agonists are summarized in Table 2. These guidelines remain unchanged since the last review. In general, the guidelines recognize that the triptans are an effective treatment option for acute migraine attacks. The EFNS guidelines state that a triptan can be efficacious even if another triptan was not.

The FDA-approved indications for the selective serotonin agonists are listed in Table 3. All of the agents are indicated for the treatment of acute migraine with or without aura. Sumatriptan subcutaneous injection is also indicated for cluster headache. The pharmacokinetics are listed in Table 4. Agents within this class have different pharmacokinetic properties, including onset and half-life, which have not necessarily translated into different clinical outcomes. The drug interaction, adverse drug event, and dosing and administration sections have been updated. The boxed warning for sumatriptan/naproxen fixed-dose combination can be found in Table 7. This warning about cardiovascular and gastrointestinal risk pertains to the naproxen component of the product.

The comparative clinical trials with the selective serotonin agonists are listed in Table 9. Numerous clinical trials have been conducted comparing the efficacy and safety of the selective serotonin agonists to placebo, as well as to each other. Several studies have found similar efficacy among the selective serotonin agonists. However, other studies have demonstrated greater efficacy with one selective serotonin agonist over another. Several new studies have been added to the clinical packet since this class was last reviewed. In 2007, two randomized controlled trials were published comparing the fixed-dose combination of sumatriptan/naproxen to

monotherapy with naproxen, sumatriptan, or placebo. The first study conducted by Brandes, et al. was a single dose study which included over 2,900 patients in two parallel groups. The primary outcome included percent of patients who were pain-free, photophobia, phonophobia, nausea, and sustained pain-free response from 2 – 24 hours post-dose. The combination product was more effective than placebo for all of the primary outcomes. The fixed-dose combination product was more effective than sumatriptan monotherapy and naproxen monotherapy for the 2 – 24 hour sustained pain-free response endpoint. There were no significant differences in the other primary outcomes between the three treatment groups. The second study conducted by Landy, et al. was a single dose study which included over 3,500 patients in two parallel groups. The primary outcome was ability to function, productivity-related impairment, and patient satisfaction. In study one, the median time to first report of normal function was similar for the fixed-dose combination and sumatriptan monotherapy treatment groups. In study two, the median time to first report of normal function was 3 hours for the fixed-dose combination group and 5 hours for the sumatriptan monotherapy and naproxen monotherapy groups, which was statistically significant.

Dr. Hisel concluded that numerous clinical trials have been conducted comparing the efficacy and safety of the selective serotonin agonists to placebo, as well as to each other. Several studies have found similar efficacy among the selective serotonin agonists. However, other studies have demonstrated greater efficacy with one selective serotonin agonist over another. Studies conducted with the fixed-dose combination product containing sumatriptan and naproxen demonstrate greater efficacy with sumatriptan/naproxen sodium compared to placebo or the monotherapy components. However, there were no studies directly comparing the efficacy or safety of the fixed-dose combination product to coadministration of sumatriptan and naproxen treatments in separate tablet formulations. There are also no published head-to-head clinical trials comparing the sumatriptan/naproxen fixed-dose combination product to other selective serotonin agonists. While agents within this class have different pharmacokinetic properties, these differences have not resulted in different clinical outcomes. Recent clinical guidelines suggest that a triptan can be efficacious even if another triptan was not. There is insufficient clinical evidence to conclude that one selective serotonin agonist is safer or more efficacious than another when administered at equivalent doses.

Therefore, all brand selective serotonin agonists within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand selective serotonin agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

At 10:00, Chairman Main asked if the Committee wanted to take a break; the Committee declined.

Antiemetics, Antihistamines: AHFS 562208

Manufacturer comments on behalf of these products:

None

Dr. Hisel commented that the antihistamine antiemetics were last reviewed in November 2006. The pathophysiology of nausea and vomiting involves multiple neurotransmitters. There are five neurotransmitter receptors that play a key role in the vomiting reflex. These include the muscarinic, dopamine, histamine, serotonin, and substance P receptors. The available antiemetic drugs antagonize these receptors, leading to improvements in nausea and vomiting. The antihistamine antiemetics can be divided into two categories: antihistaminic-anticholinergic agents and phenothiazines. The antihistaminic-anticholinergic agents consist of dimenhydrinate, meclizine and trimethobenzamide. They interrupt various visceral afferent pathways that stimulate nausea and vomiting. Prochlorperazine is the only phenothiazine in this class. Phenothiazines block dopamine receptors located in the chemoreceptor trigger zone (CTZ). Table 1 lists the antihistamine antiemetics that are included in this review. All agents are available in a generic formulation. Dimenhydrinate and meclizine are also available over-the-counter.

The guidelines that incorporate the use of the antihistamine antiemetics are summarized in Table 2. These guidelines focus on the use of antiemetic agents in oncology, pregnancy, during the postoperative period, and for use in treating general nausea and vomiting. The National Comprehensive Cancer Network antiemesis guidelines have recently been updated in 2009. The other guidelines have not changed since this class was last reviewed. Prochlorperazine is the only antihistamine antiemetic specifically mentioned in the oncology guidelines. It is generally reserved for patients receiving low and minimal emetic risk chemotherapy, intermediate emetic risk radiation therapy, or as an adjunct to the antiemetic regimen in patients experiencing emesis despite proper prophylaxis. Guidelines also state that the antihistamine antiemetics are generally safe and effective in pregnancy-induced nausea and vomiting. Dimenhydrinate and prochlorperazine may be effective for post-operative nausea and vomiting. Finally, guidelines identify a role for the antihistamine antiemetics in the treatment of nausea and vomiting associated with motion sickness and vertigo.

The FDA-approved indications for the antihistamine antiemetics are listed in Table 3, which include the treatment of motion sickness, peripheral vertigo, general and post-operative nausea and vomiting. The pharmacokinetic, drug interaction, adverse drug event, and dosing and administration sections have been updated.

The comparative clinical trials with the antihistamine antiemetics are listed in Table 8. Although there are limited head-to-head clinical trials using the antihistamine antiemetics, available studies show no significant differences in terms of relative efficacy and safety of these agents. A literature search did not reveal any new published clinical trials with the antihistamine antiemetics since the last review.

Dr. Hisel concluded that the antihistamine antiemetics are an effective treatment option for the management of nausea and vomiting. Current guidelines recommend the use of these agents for nausea and vomiting associated with motion sickness and vertigo. Antihistamine antiemetics may also be considered in the management of acute or breakthrough episodes of nausea and vomiting of pregnancy. While antihistamine antiemetics are not recommended as first-line therapy for the prevention of post-operative nausea and vomiting, several studies have reported that dimenhydrinate was as effective as 5-HT₃ receptor antagonists and droperidol. Oncology guidelines state that prochlorperazine is an accepted treatment option to prevent emesis in patients receiving low and minimal emetic risk chemotherapy, as well as intermediate emetic risk radiation therapy. Although there are limited head-to-head clinical trials using the antihistamine antiemetics, available studies show no significant differences in terms of relative efficacy and safety of these agents.

Therefore, all brand antihistamine antiemetics within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand antihistamine antiemetic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Antiemetics, 5-HT₃ Receptor Antagonists: AHFS 562220

Manufacturer comments on behalf of these products:

None

Dr. Hisel commented that the 5-HT₃ receptor antagonists were last reviewed in November 2006. Several neurotransmitter receptor sites play a key role in the vomiting reflex. The 5-HT₃ receptor antagonists block the serotonin receptors in both the gastric area and the chemoreceptor trigger zone, thereby disrupting the signal to vomit and reduce the sensation of nausea. Table 1 lists the 5-HT₃ receptor antagonists that are included in this review. Granisetron and ondansetron have become available in a generic formulation since this class was last reviewed.

The guidelines that incorporate the use of the 5-HT₃ receptor antagonists are summarized in Table 2. These are the same guidelines that were reviewed in the antihistamine antiemetic class review. The 5-HT₃ receptor antagonists are considered first-line therapy as part of a three-drug combination for the prevention of acute emesis associated with moderately or highly emetogenic chemotherapy. They are also considered as one of several treatment options to prevent delayed emesis for moderately emetogenic chemotherapy. According to the National Comprehensive Cancer Network antiemesis guidelines, all four 5-HT₃ receptor antagonists are considered to have similar effectiveness for the control of acute emesis. These agents can also be administered with or without a corticosteroid for radiation-induced nausea and vomiting. According to the American College of Obstetricians and Gynecologists guidelines, the evidence is limited on the safety and efficacy of the 5-HT₃ receptor antagonists for nausea and vomiting of pregnancy. The International Anesthesia Research Society guidelines for managing post-operative nausea and vomiting state there is no evidence of any difference in the efficacy and safety of the 5-HT₃ receptor antagonists in the prophylaxis of post-operative nausea and vomiting.

The FDA-approved indications for the 5-HT₃ receptor antagonists are listed in Table 3. All four agents are approved for chemotherapy-induced and post-operative nausea and vomiting. Only granisetron and ondansetron are approved for radiation-induced nausea and vomiting. The pharmacokinetic, drug interaction, adverse drug event, and dosing and administration sections have been updated as necessary.

The comparative clinical trials with the 5-HT₃ receptor antagonists are listed in Table 8. Several new studies for chemotherapy-induced and post-operative nausea and vomiting have been added to the clinical packet. A large number of clinical trials have demonstrated similar efficacy and safety among the 5-HT₃ receptor antagonists for the treatment of chemotherapy-induced nausea and vomiting. Granisetron and ondansetron have demonstrated similar efficacy in one clinical trial for radiation-induced nausea and vomiting. Clinical trials have also demonstrated similar efficacy among the agents for the treatment of post-operative nausea and vomiting.

Dr. Hisel concluded that the 5-HT₃ receptor antagonists are considered first-line therapy as part of a three-drug regimen for the prevention of acute emesis associated with moderately or highly emetogenic chemotherapy. A large number of clinical trials have demonstrated similar efficacy and safety among the 5-HT₃ receptor antagonists for the treatment of chemotherapy-induced nausea and vomiting and guidelines do not give preference to one agent over another for this indication. Granisetron and ondansetron are indicated for the treatment of RINV and have demonstrated similar efficacy in one clinical trial. The 5-HT₃ receptor antagonists have demonstrated similar efficacy for the treatment of post-operative nausea in clinical trials. According to current guidelines, there is no evidence of any difference in the efficacy and safety profiles of the 5-HT₃ receptor antagonists in the prophylaxis of post-operative nausea.

Therefore, all brand 5-HT₃ receptor antagonists within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand 5-HT₃ receptor antagonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Antiemetics, Miscellaneous: AHFS 562292

Manufacturer comments on behalf of these products:

None

Dr. Hisel commented that the miscellaneous antiemetics were last reviewed in November 2006 and are listed in Table 1. Aprepitant is a selective antagonist of the substance P receptor; fosaprepitant is a prodrug of aprepitant. Dronabinol and nabilone are orally active cannabinoids, which have complex effects on the central nervous system. Scopolamine acts as an anticholinergic agent. Only dronabinol is available in a generic formulation.

The guidelines that incorporate the use of the miscellaneous antiemetics are summarized in Table 2. These are the same guidelines included in the last two class reviews. Aprepitant or fosaprepitant is considered first-line therapy as part of a three-drug combination for the prevention of acute emesis associated with moderately or highly emetogenic chemotherapy. According to the National Comprehensive Cancer Network antiemesis guidelines, dronabinol, nabilone, and aprepitant are also effective treatment options for breakthrough nausea and vomiting associated with chemotherapy. The International Anesthesia Research Society guidelines on post-operative nausea and vomiting state that transdermal scopolamine has an antiemetic effect if it is applied the evening before surgery or 4 hours before the end of anesthesia. These same guidelines state that nabilone and dronabinol have not shown antiemetic efficacy in the post-operative nausea and vomiting setting.

The FDA-approved indications for the miscellaneous antiemetics are listed in Table 3, which include the treatment of chemotherapy-induced nausea and vomiting, postoperative nausea and vomiting, and motion sickness. Dronabinol is the only miscellaneous antiemetic indicated for the treatment of AIDS-related anorexia. The pharmacokinetic, drug interaction, adverse drug event, and dosing and administration sections have been updated as necessary.

The comparative clinical trials with the miscellaneous antiemetics are listed in Table 8. Several new studies for chemotherapy-induced nausea and post-operative nausea and vomiting have been added to the clinical packet. There is a lack of head-to-head clinical trials with agents in this class. Several clinical trials for chemotherapy-induced nausea have demonstrated greater efficacy using a triple therapy regimen (aprepitant, 5-HT₃ receptor antagonist, and dexamethasone), as compared to a dual therapy regimen (5-HT₃ receptor antagonist and dexamethasone). Although there are no head-to-head clinical trials comparing the miscellaneous antiemetics in the post-operative setting, scopolamine and aprepitant have demonstrated similar efficacy compared to ondansetron. Clinical studies have demonstrated that both the oral and transdermal scopolamine products are effective in the treatment of motion sickness. Clinical trials have shown that dronabinol increases appetite in AIDS patients- but does not consistently produce weight gain. Megestrol acetate, which is available in a generic formulation, was shown to be more effective than dronabinol for improving appetite and producing weight gain. Adding dronabinol to megestrol acetate produced no additional clinical benefits.

Dr. Hisel concluded that aprepitant or fosaprepitant is considered first-line therapy as part of a three-drug combination for the prevention of acute emesis associated with moderately or highly emetogenic chemotherapy. Clinical trials have demonstrated greater efficacy using a triple therapy regimen than a dual therapy regimen. Dronabinol, nabilone, and aprepitant are also effective treatment options for breakthrough nausea and vomiting associated with chemotherapy. Aprepitant and scopolamine are an effective treatment option for post-operative nausea and vomiting and have demonstrated similar efficacy compared to ondansetron. Scopolamine is the only miscellaneous antiemetic indicated for the treatment of motion sickness and both the oral and transdermal products have been found to be effective. There is a lack of head-to-head clinical trials with agents in this class. Dronabinol is the only miscellaneous antiemetic indicated for the treatment of AIDS-related anorexia. Megestrol acetate was shown to be more effective than dronabinol and adding dronabinol to megestrol acetate produced no additional clinical benefits.

Therefore, all brand miscellaneous antiemetics within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use. Aprepitant is considered first-line therapy in certain clinical settings, such as in patients receiving moderately or highly emetogenic chemotherapy. Therefore, patients with a cancer diagnosis should be allowed approval for aprepitant through the medical justification portion of the prior authorization process, as well as automatic approval through the electronic prior authorization process.

No brand miscellaneous antiemetic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Proton-pump Inhibitors Single Entity Agents: AHFS 562836

Manufacturer comments on behalf of these products:

None

Dr. Hisel commented that the single entity proton-pump inhibitors were last reviewed in November 2006. The proton-pump inhibitors are a class of antisecretory compounds that suppress gastric acid secretion and are

generally recognized as the most potent acid suppressants available. Proton-pump inhibitors will only inhibit proton pumps that are actively secreting acid. Following a meal, approximately 70-80% of the proton pumps will be active. Thus, single doses of proton-pump inhibitors will not completely inhibit acid secretion and subsequent doses are required to inhibit previously inactive proton pumps and newly regenerated pumps. With regular dosing, maximal acid suppression occurs in 3-4 days. The primary differences between the proton-pump inhibitors occur in their pharmacokinetic and pharmacodynamic properties along with formulation availability. Table 1 lists the single entity proton-pump inhibitors that are included in this review. Omeprazole and pantoprazole are available in a generic formulation. Omeprazole is also available over-the-counter (OTC). The OTC omeprazole products are currently on the Preferred Drug List. However, the prescription omeprazole products require prior authorization. Generic pantoprazole also requires prior authorization.

The guidelines that incorporate the use of the single entity proton-pump inhibitors are summarized in Table 2. The guidelines pertain to gastroesophageal reflux disease (GERD), eradication of *H. pylori*, and dyspepsia. The American Gastroenterological Association medical position statement on the management of gastroesophageal reflux disease was updated in 2008. The other GERD guidelines have remain unchanged since this class was last reviewed. In general, the guidelines recognize that the proton-pump inhibitors are more effective than H₂-receptor antagonists for the treatment of erosive esophagitis and symptomatic GERD. The *H. pylori* guidelines recommend proton-pump inhibitors in combination with antibiotics as first-line therapy for the eradication of *H. pylori* infection as either a triple therapy or quadruple therapy regimen.

The FDA-approved indications for the single entity proton pump inhibitors are listed in Table 3, which includes treatment of duodenal and gastric ulcers, erosive esophagitis, symptomatic GERD, frequent heartburn, hypersecretory conditions, and reduction of risk of upper gastrointestinal bleeding in critically ill patients. The pharmacokinetic, drug interaction, adverse drug event, and dosing and administration sections have been updated as necessary. Esomeprazole, lansoprazole, and omeprazole are the only proton-pump inhibitors indicated for the treatment of pediatric patients as young as one year of age.

The comparative clinical trials with the single entity proton-pump inhibitors are listed in Table 8. Several new studies have been added to the clinical packet on the treatment of GERD and peptic ulcer disease since this class was last reviewed. Numerous clinical trials have demonstrated equal efficacy among the various proton-pump inhibitors for the treatment of erosive esophagitis and symptomatic GERD. However, some studies have demonstrated various degrees of greater efficacy with one proton-pump inhibitor over another in the treatment of these disorders. Several clinical trials and meta analyses have demonstrated similar efficacy among the various proton-pump inhibitors for the treatment of *H. pylori* infection.

Dr. Hisel concluded that the single entity proton-pump inhibitors are an effective treatment option for a variety of acid-related disorders, including erosive esophagitis, symptomatic GERD, and peptic ulcer disease. Guidelines recognize that the proton-pump inhibitors are more effective than H₂-receptor antagonists and are first-line treatment in combination with antibiotics for the eradication of *H. pylori* infection. Clinical guidelines do not give preference of one proton-pump inhibitor over another. Numerous clinical trials have demonstrated equal efficacy among the various proton-pump inhibitors for the treatment of erosive esophagitis and symptomatic GERD. Some studies have demonstrated various degrees of greater efficacy with one agent over another; however, close analysis of these studies show that the overall differences are small, often ranging from 3-9%. Though the results are statistically significant, the clinical significance of these differences is not clear. It should be noted that most of the comparative trials of the proton-pump inhibitors evaluated FDA-approved doses. However, therapeutically equivalent doses of the proton-pump inhibitors have not been well established.

Several clinical trials and meta analyses have demonstrated similar efficacy among the various proton-pump inhibitors for the treatment of *H. pylori* infection.

Therefore, all brand single entity proton-pump inhibitors within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand single entity proton-pump inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Proton-pump Inhibitors Combination Products: AHFS 562836

Manufacturer comments on behalf of these products:

None

Dr. Hisel commented that the combination proton-pump inhibitors were last reviewed in November 2006. Currently, only one branded product is available and is listed in table 1. Prevpac[®] is supplied as individual daily administration cards, each containing two lansoprazole capsules, four amoxicillin capsules, and two clarithromycin tablets. All components are commercially available in separate formulations and the amoxicillin and clarithromycin components are available generically.

The guidelines that incorporate the use of the combination proton-pump inhibitors are summarized in Table 2. These include guidelines on the eradication of *H. pylori* infection, which are the same guidelines reviewed with the single entity agents.

The FDA-approved indications for the combination proton-pump inhibitors are listed in Table 3. Prevpac[®] is only indicated for the treatment of patients with *H. pylori* infection and duodenal ulcer disease to eradicate *H. pylori*. The pharmacokinetic, drug interaction, adverse drug event, and dosing and administration sections have been updated as necessary.

The comparative clinical trials with the combination proton-pump inhibitors are listed in Table 8. Clinical trials comparing triple therapy (lansoprazole, amoxicillin, and clarithromycin) to dual therapy (lansoprazole with amoxicillin or clarithromycin) and lansoprazole monotherapy found that triple therapy provides significantly greater eradication rates of *H. pylori*. Meta analyses have demonstrated similar efficacy among the various proton-pump inhibitors regimens for the treatment of *H. pylori* infection.

Dr. Hisel concluded that the only combination proton-pump inhibitor product available, Prevpac[®], contains lansoprazole capsules, amoxicillin capsules, and clarithromycin tablets as separate dosage forms in an individual daily administration card. Each of the components is commercially available in separate formulations and the amoxicillin and clarithromycin components are available generically. Clinical trials found that triple therapy with lansoprazole and two antibiotics provides significantly greater eradication rates of *H. pylori* than dual therapy or monotherapy. Meta analyses have demonstrated similar efficacy among the various proton-pump inhibitor regimens for the treatment of *H. pylori* infection. Guidelines recommend proton-pump inhibitors

in combination with antibiotics as first-line therapy for the eradication of *H. pylori* infection, and do not give preference to one proton-pump inhibitor over another.

Therefore, all brand combination proton-pump inhibitors within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand combination proton-pump inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Dr. Culpepper asked if there were studies comparing Prevpac[®] to the individual components given as separate prescriptions. Dr. Hisel stated she was not aware of any studies, but that she would review the methods sections of the studies and provide the Committee with that information. Dr. Culpepper then asked what the prior authorization criteria are for Prevpac[®]. Dr. Littlejohn reviewed the prior authorization criteria, which was contained in the clinical packet.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

6. NEW BUSINESS

Chairman Main recognized Dr. Littlejohn. She reminded the manufacturers that cost proposals are accepted by Medicaid 365 days per year.

Dr. Littlejohn pointed out to Committee members that the boxed warning updates are now included as a supplemental handout in the materials they receive at the meetings. She also informed the Committee members that they have been signed up to receive the FDA MedWatch e-mail service. Any members not receiving these e-mails should contact Dr. Littlejohn or Ms. Thomas.

7. RESULTS OF VOTE ANNOUNCED

Dr. Littlejohn announced the results of voting for each of the therapeutic classes and announced that all classes were approved as recommended. Results of voting are described in the Appendix to the minutes.

8. NEXT MEETING DATE

The next P&T Committee Meeting is scheduled for 9:00 a.m. on May 13, 2009 at the Alabama State Capitol Auditorium. August 12, 2009 is the third meeting date for 2009. Details regarding the August meeting will be given at a later time.

9. ADJOURN

There being no further business, Ms. Faulk moved to adjourn, and Dr. Culpepper seconded.

The meeting was adjourned at 10:28 a.m.

Appendix

RESULTS OF THE BALLOTING Alabama Medicaid Agency Pharmacy and Therapeutics Committee February 11, 2009

A. Recommendation: No brand centrally acting skeletal muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended



Medical Director



Approve



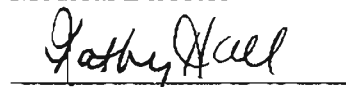
Approve as amended



Disapprove



No action



Deputy Commissioner



Approve



Approve as amended



Disapprove



No action



Commissioner



Approve



Approve as amended



Disapprove

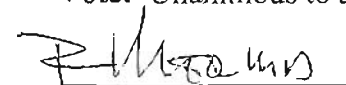


No action

B. Recommendation: No brand direct-acting skeletal muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended



Medical Director



Approve



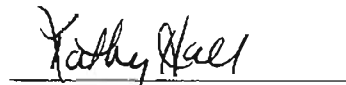
Approve as amended



Disapprove



No action



Deputy Commissioner



Approve



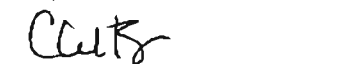
Approve as amended



Disapprove



No action



Commissioner



Approve



Approve as amended



Disapprove

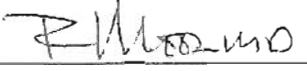


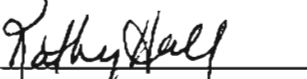
No action

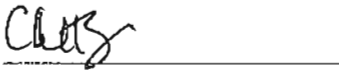
C. **Recommendation:** No brand GABA-derivative skeletal muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

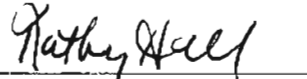
 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner


D. **Recommendation:** No brand miscellaneous skeletal muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

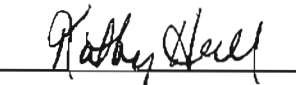
 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

E. Recommendation: No brand opiate agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

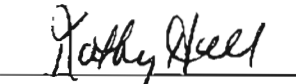
 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

F. Recommendation: No brand partial opiate agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

G. Recommendation: No brand selective serotonin agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Phil Moore MD

Medical Director

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Kathy Hall

Deputy Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Chris

Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

H. Recommendation: No brand antihistamine antiemetic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Phil Moore MD

Medical Director

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Kathy Hall

Deputy Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Chris


Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

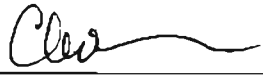
- I. Recommendation:** No brand 5-HT₃ receptor antagonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

- J. Recommendation:** No brand miscellaneous antiemetic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

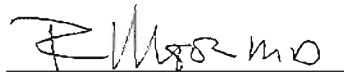
 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

 ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

K. Recommendation: No brand single entity proton-pump inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended



Medical Director



Approve



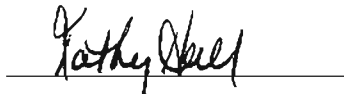
Approve as amended



Disapprove



No action



Deputy Commissioner



Approve



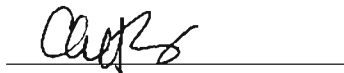
Approve as amended



Disapprove



No action



Commissioner



Approve



Approve as amended



Disapprove



No action

L. Recommendation: No brand combination proton-pump inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended



Medical Director



Approve



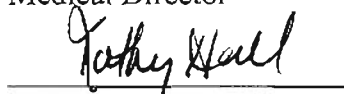
Approve as amended



Disapprove



No action



Deputy Commissioner



Approve



Approve as amended



Disapprove



No action



Commissioner



Approve



Approve as amended



Disapprove



No action

Respectfully submitted,



Tina Hisel, Pharm.D., BCPS

February 11, 2009

Date